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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,150	11/17/2003	Lilip Lau	PARCR 67359	4295

7590 09/27/2006

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EXAMINER
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GILBERT, SAMUEL G

ART UNIT	PAPER NUMBER
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3735

DATE MAILED: 09/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/715,150

Applicant(s)

LAU ET AL.

Examiner

Samuel G. Gilbert

Art Unit

3735

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 20-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-19 is/are rejected.
- 7) ☒ Claim(s) 2 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: ____  |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :7/8/2004, 11/3/2004(first), 11/3/2004(second), 1/11/2005, 2/8/2005, 2/28/2005,8/10/2005, 8/12/2005, and 3/9/2006 .

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-19, drawn to method and apparatus for delivering a cardiac harness, classified in class 600, subclass 37.
- II. Claims 20-22, drawn to introducer sleeve, classified in class 606, subclass 264.
- III. Claims 23-25, drawn to loading assistance apparatus, classified in class 128, subclass 897.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In the instant case, subcombination II has separate utility such as use for introduction of an aspiration device. See MPEP § 806.05(d).

The examiner has required restriction between subcombinations usable together. Where applicant elects a subcombination and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a

claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Inventions I and III are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In the instant case, subcombination III has separate utility such as loading a mesh for hernia repair. See MPEP § 806.05(d).

The examiner has required restriction between subcombinations usable together. Where applicant elects a subcombination and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with John Nagy on 9/14/2006 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-19. Affirmation of this election must be made by applicant in replying to this Office action. Claims 20-25 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### ***Information Disclosure Statement***

The information disclosure statements filed 7/8/2004, 11/3/2004(first), 11/3/2004(second), 8/10/2005 and 3/9/2006 have been considered. The information disclosure statements filed 1/11/2005, 2/8/2005, 2/28/2005, and 8/10/2005 have not been considered because they appear to be duplicates of previously filed information disclosure statements.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 3735

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 6, 7, and 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Vanden Hoek et al (6,293,906).

Claim 1 - element -39- is an elongate body, elements -36b- are push rods, element -10- is a cardiac harness and element -42- is a releasing member.

Claim 3 - handle -32- is a positioning arrangement.

Claim 6 - element -36b- is a support member and cardiac harness -10- is attached by line -42-. The loops are considered interconnected with the cardiac harness and support members -36b-.

Claim 7 - element -42- is severed to release the cardiac harness, therefore it is the examiner's position that the element -42- is inherently anchored to prevent release of the cardiac harness. The examiner is taking the severing of element -42- as releasing element -42- from the anchoring member.

Claim 9 - element -39- is an elongate body, element -36b- is a support member and cardiac harness -10- is attached by line -42-. Plastic knobs -34- are used to provide reduced frictional forces as claimed.

Claim 10 - the pushrods -36b- splay outwards.

Claim 11- the push rods are canted outwards, column 9 lines 29 and 30.

Claims 1, 3, and 5-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Tovey (5,405,360).

Claim 1 - element -18- is an elongate member, elements -11- are push rods, element -17- is a cardiac harness, and suture -22- is a releasing member.

Claim 3 - rotation means -21- is a positioning arrangement.

Claim 5 - element -19- is a handle and trigger means -20- is a control assembly.

Claim 6 - elements -11- are support members, element -17- is a cardiac harness, and suture -22- is a releasing stitch.

Claim 7 - column 8, sets forth a trigger as an anchoring member.

Claim 8 - a trigger inherently is capable of the of the movement as claimed.

Claim 9 - element -18- is an elongate member, elements -11- are push rods, element -17- is a cardiac harness, and suture -22- is a releasing member and members -14- provide a configuration capable of performing the function as recited.

Claims 10 and 11 - the push rods splay outwards and are canted. Applicant's attention is invited to figure 5.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.



Claims 12-19 - are rejected under 35 U.S.C. 103(a) as being unpatentable over Vanden Hoek et al (6,293,906) in view of Tovey (5,405,360).

Claim 12 and 14 -19 - Vanden Hoek et al teaches a method as claimed but does not teach disconnecting the harness from the support member without cutting the line, the suture is severed, column 11 lines 15-17. Tovey et al teaches the use of a device with a plurality of pushrods and a surgical mesh attached thereto with a suture. Tovey et al teaches that the suture may be passed through the device and manually released or released by a trigger, column 8 lines 43-49. It would have been obvious to one of ordinary skill in the medical arts at the time the invention was made to provide the device of Vanden Hoek et al with a trigger release device and allowing the suture to be released externally as taught by Tovey as a substitution of functionally equivalent elements.

Claim 13 - it is the examiners position that the trigger of Tovey would inherently be connected to a "retention loop".

Claims 1 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taheri (6,620,095) in view of Vanden Hoek et al (6,293,906).

Claim 1 - Taheri teaches an elongate member -4-, a plurality of pushrods -18-, and cardiac harness -12-, however pockets are used to connect the harness to the pushrods. Vanden Hoek et al teaches the use of pockets or a suture/eyelets to connect the cardiac harness to the pushrods as functional equivalents, figures 8 and 12. It would have been obvious to one of ordinary skill in the medical arts at the time the

invention was made to use the suture/eyelet connection means in place of the pockets taught Taheri as an obvious design expedient of selecting among well known equivalents.

Claims 3 and 4 - element -24- is a suction cup.

Claim 5 - it is the examiner's position that the device of Taheri inherently requires a handle and a control assembly to deploy the arms -18-.

Claim 6 - the rods -18 are considered a support member, a suture(stitch) is used to connect the cardiac support to the arms.

Claim 7 - the suture is inherently require to be connected to an anchoring member.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Taheri (6,620,095) in view of Vanden Hoek et al (6,293,906) as applied to claims 1 and 3-6 above, and further in view of Tovey (5,405,360).

The combination of Taheri and Vanden Hoek et al teaches an apparatus as claimed but does not teach a release member as claimed. Tovey et al teaches the use of a device with a plurality of pushrods and a surgical mesh attached thereto with a suture. Tovey et al further teaches that the suture may be passed through the device and manually released or released by a trigger, column 8 lines 43-49. It would have been obvious to one of ordinary skill in the medical arts at the time the invention was made to provide the device of Taheri and Vanden Hoek et al with a trigger release

device and allowing the suture to be released externally as taught by Tovey et al to gain the advantage of controlling the releasing of cardiac support externally as taught by Tovey et al.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 3-19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,579,226. Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences are obvious modifications to the scope of the claims.

Claims 1 and 3-19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21-25 of copending Application No. 11/109,528. Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences are obvious modifications in the scope of the claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

#### ***Allowable Subject Matter***

Claim 2 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

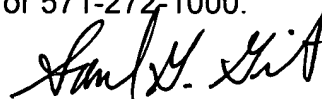
#### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel G. Gilbert whose telephone number is 571-272-4725. The examiner can normally be reached on Monday-Friday 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3735

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Samuel G. Gilbert  
Primary Examiner  
Art Unit 3735

sgg